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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,283	07/15/2005	Hans-Ulrich Petereit	273014US0PCT	5271

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/542,283	PETEREIT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 12-23* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7 and 12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 09/02/08 are acknowledged.

2. Claims 1-4 were withdrawn.

3. Claims 8-11 were cancelled.

4. Claims 12-23 were added.

5. Claims 5-7 and 12-23 are included in the prosecution.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 07/24/08 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Response to Arguments

Rejection of claims 5-7 and 10-11 under 35 USC § 103(a)

7. Applicant's arguments, see Page 9, filed 09/02/08, with respect to the rejection of claims 5-7 and 10-11 under 35 USC § 103(a) as being unpatentable over Petereit et al. (US 2003/0064036) in view of Bourns et al. (US 5,529,800) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kajiyama et al. (US 5,545,492 B2) and Smith et al. (US 6,194,000 B1).

Claim Objections

8. Claim 13 is objected to because of the following informalities: "dimentylaminoethyl" should be spelled "dimethylaminoethyl". Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 5-7, 12-15 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajiyama et al. (US 5,545,492 B2).

The claimed invention is a powder with an average particle size of 200 μm or less, comprising (a) an anionic active pharmaceutical ingredient, (b) a copolymer which consists of free-radical polymerized C_1 to C_4 esters of acrylic or methacrylic acid and further (meth)acrylate monomers which have functional tertiary amino groups, and (c) 5 to 50% by weight, based on (b), of a C_{12} to C_{22} carboxylic acid, (d) with the proviso that less than 3% by weight based on the copolymer of an emulsifier having an HLB of at least 14 is present, wherein the powder when placed in the mouth immediately disintegrates and releases active ingredient (a).

Kajiyama teaches a quick disintegrating tablet in the buccal cavity comprising drug-containing particles with a mean particle diameter of approximately 50 ~ approximately 250μm, the drug-containing particles contain a bitter tasting drug and a

pharmaceutical preparation carrier (Col. 1, lines 14-24). The "quick disintegrating tablet in buccal cavity" means "a tablet that is disintegrated in the buccal cavity within 1 minute by essentially saliva only without taking water for swallowing tablets" (Col. 5, lines 48-51). The bitter tasting drugs include ibuprofen (Col. 6, lines 38-42 and Col. 7, line 18). The pharmaceutical preparation carrier includes gastrosoluble acrylic polymers, such as methyl methacrylate-butyl methacrylate-dimethyl aminoethyl methacrylate copolymer (for instance, brand name EUDRAGIT E, Rohm Co., Ltd.) (Col. 8, lines 11-26). Higher fatty acids such as stearic acid, lauric acid, myristic acid, and palmitic acid are disclosed (Col. 8, lines 38-41). Kajiyama teaches the advantages of the drug-containing particles as including alleviating the bitter taste of bitter tasting drugs and having the ability to quickly disintegrate and dissolve in the buccal cavity (Col. 6, lines 8-18).

Kajiyama does not expressly teach the weight percent of the carboxylic acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a quick disintegrating tablet with drug particles comprising a bitter tasting drug such as ibuprofen and gastrosoluble acrylic polymers (such as methyl methacrylate-butyl methacrylate-dimethyl aminoethyl methacrylate copolymer) and higher fatty acids such as stearic acid, as taught by Kajiyama, modify the level of higher fatty acids such as stearic acid during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would do this because the level of higher fatty acids is a manipulatable parameter which can be modified during the process of routine experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 5, the active ingredient-containing powder with an average particle size of 200 μm or less would have been obvious over the drug-containing particles with a mean particle diameter of approximately 50 ~ approximately 250μm, as taught by Kajiyama (Col. 1, lines 14-24). The limitation of (a) an anionic active pharmaceutical ingredient would have been obvious over the ibuprofen taught by Kajiyama (Col. 6, lines 38-42 and Col. 7, line 18). The limitation of (b) a copolymer which consists of free-radical polymerized C_1 to C_4 esters of acrylic or methacrylic acid and further (meth)acrylate monomers which have functional tertiary amino groups would have been obvious over the gastrosoluble acrylic polymers, such as methyl methacrylate-butyl methacrylate-dimethyl aminoethyl methacrylate copolymer (for instance, brand name EUDRAGIT E, Rohm Co., Ltd.) taught by Kajiyama (Col. 8, lines 11-26). The limitation of (c) 5 to 50% by weight, based on (b), of a C_{12} to C_{22} carboxylic acid would have been obvious over the higher fatty acids such as stearic acid, lauric acid, myristic acid, and palmitic acid taught by Kajiyama (Col. 8, lines 38-41). One of ordinary skill in the art would modify the level of these fatty acids in the composition during the process of routine experimentation and the recited weight percent range would have been an obvious variant unless there is evidence of criticality or unexpected

results. The proviso that less than 3% by weight based on the copolymer of an emulsifier having an HLB of at least 14 is present would have been obvious because "less than 3%" includes 0%, and there is no teaching of emulsifier or surfactant in the drug-containing particles taught by Kajiyama (Col. 1, lines 14-24). The limitation of the powder when placed in the mouth immediately disintegrates and releases active ingredient (a) would have been obvious over the "quick disintegrating tablet in buccal cavity" means "a tablet that is disintegrated in the buccal cavity within 1 minute by essentially saliva only without taking water for swallowing tablets" (Col. 5, lines 48-51).

Regarding instant claims 6-7, the limitation of the anionic analgesic and anionic antirheumatic would have been obvious over the ibuprofen, which is a known analgesic and antirheumatic, as taught by Kajiyama (Col. 7, line 18).

Regarding instant claims 12 and 13, the limitation of the anionic active pharmaceutical ingredient (a) that has been incorporated into the copolymer (b) would have been obvious over the particles containing a bitter tasting drug and a pharmaceutical preparation carrier (Col. 1, lines 14-24), where the pharmaceutical preparation carrier includes gastrosoluble acrylic polymers, such as methyl methacrylate-butyl methacrylate-dimethyl aminoethyl methacrylate copolymer (for instance, brand name EUDRAGIT E, Rohm Co., Ltd.), as taught by Kajiyama (Col. 8, lines 11-26).

Regarding instant claim 14, the limitation of the carboxylic acid would have been obvious over the higher fatty acids such as stearic acid, lauric acid, myristic acid, and palmitic acid, as taught by Kajiyama (Col. 8, lines 38-41).

Regarding instant claim 15, the limitation of the powder that contains no emulsifier having an HLB of 14 or more would have been obvious because there is no teaching of emulsifier or surfactant in the drug-containing particles taught by Kajiyama (Col. 1, lines 14-24).

Regarding instant claim 18, the limitation of the bitterness value would have been obvious over the drug-containing particles that alleviate the bitter taste of bitter tasting drugs and quickly disintegrate and dissolve in the buccal cavity (within 1 minute), as taught by Kajiyama (Col. 6, lines 8-18, Col. 16, Table 1, and Col. 5, lines 48-51). One of ordinary skill in the art would determine the bitterness value using the standard methodology during the process of routine experimentation.

Regarding instant claims 19-20, the limitation of at least one pharmaceutically acceptable excipient would have been obvious over the lubricants such as magnesium stearate taught by Kajiyama (Col. 10, lines 12-13). One of ordinary skill in the art would use magnesium stearate because it is a commonly used lubricant in tablet formulations. The HLB of magnesium stearate is a property of the lubricant that is implicit with the inclusion of magnesium stearate in the composition. Please see MPEP 2112.01. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Regarding instant claim 21, the limitation of a plasticizer would have been obvious over the plasticizers triacetin, triethyl citrate, and dibutyl sebacate as taught by Kajiyama (Col. 8, lines 48-51).

Regarding instant claim 22, the limitation of the form of the composition would have been obvious over the quick disintegrating tablet (Col. 1, lines 14-24) produced by molding under pressure to retain the tablet form (Col. 11, lines 3-6), as taught by Kajiyama.

Instant claim 23 is set forth in the form of a product-by-process claim, which is considered a product claim by the Office. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. In *re Thorpe et al.* (CAFC 1985), supra; In *re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; Tri-Wall Containers, Inc. v. United States et al. (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; In re Brown et al. (CCPA 1972) 450 F2d 531, 173 USPQ 685; Ex parte Edwards et al. (BPAI 1986) 231 USPQ 981. Instant claim 23 would have been obvious over the quick disintegrating tablet (Col. 1, lines 14-24) produced by molding under pressure to retain the tablet form (Col. 11, lines 3-6), as taught by Kajiyama.

11. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajiyama et al. (US 5,545,492 B2) in view of Smith et al. (US 6,194,000 B1).

The teaching of Kajiyama is stated above.

Kajiyama does not expressly teach a powder that contains an emulsifier having an HLB of at least 14.

Smith teaches immediate release particles of an NMDA receptor antagonist admixed with sodium lauryl sulfate (Col. 2, lines 2-3 and Col. 3, lines 29-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a quick disintegrating tablet with drug particles comprising a bitter tasting drug such as ibuprofen and gastrosoluble acrylic polymers (such as methyl methacrylate-butyl methacrylate-dimethyl aminoethyl methacrylate copolymer) and higher fatty acids such as stearic acid, as taught by Kajiyama, combine it with the use of sodium lauryl sulfate in immediate release particles, as taught by Smith, and produce the instant invention.

One of ordinary skill in the art would do this because incorporating sodium lauryl sulfate into immediate release drug particles is known in the art, as evidenced by Smith.

Regarding instant claims 16-17, the limitations of 1-3% emulsifier having an HLB of 14 or more and the limitation of 1-2% emulsifier having an HLB of 14 or more would have been obvious over the use of sodium lauryl sulfate (a known emulsifier) in immediate release particles, as taught by Smith (Col. 2, lines 2-3 and Col. 3, lines 29-36).

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615